

The opinion in support of the decision being entered today was not written
for publication and is not binding precedent of the Board.

Paper No. 27

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte REID W. von BORSTEL and MICHAEL K. BAMAT

Appeal No. 2002-0891
Application No. 08/460,186

ON BRIEF

MAILED

APR 30 2002

**PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES**

Before WINTERS, WILLIAM F. SMITH and MILLS Administrative Patent Judges,
MILLS, Administrative Patent Judge.

ON REMAND TO THE EXAMINER

Our consideration of the record leads us to conclude that this case is not in
condition for a decision on appeal. Accordingly, we remand the application to the
examiner to consider the following issues and take appropriate action.

PROCEDURAL HISTORY

A final rejection was issued in the application on September 13, 1999 (Paper No. 15). The final rejection included a provisional rejection of claims 1-25 for obviousness-type double patenting in view of the claims of five copending applications. See also Paper No 5, page 2. The examiner, at the request of appellants, held these rejections in abeyance until "it is known which claims are deemed allowable". Paper No. 8, page 2. The Examiner's Answer (Paper No. 21) failed to address the provisional rejections held in abeyance.

In this case the examiner had two options with regard to the provisional double patenting rejections. The rejections should have either been maintained or dropped. In our view, the better practice would be to maintain such provisional double patenting rejections and repeat them, as appropriate, in the Answer. Failing to mention the provisional double patenting rejections in the Answer creates a procedural anomaly on Appeal, requiring further action on the part of the examiner.

Claim 1 is representative of the claims on appeal and reads as follows:

1. A method for preventing or treating toxicity due to a pyrimidine nucleoside analog comprising administering to an animal a pharmaceutically effective amount of an acylated derivative of a non-methylated pyrimidine nucleoside.

The references relied upon by the examiner are:

Hanze et al. (Hanze) 4,017,606 Apr. 12, 1977

von Borstel et al. (von Borstel) WO 89/03837 May 5, 1989

Sommadossi et al. (Sommadosi), "Uridine Reverses the Toxicity of 3'-Azido-3'-

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Deoxythymidine in Normal Human Granulocyte-Macrophage Progenitor Cells in Vitro

Without Impairment of Antiretroviral Activity," Antimicrobial Agents and Chemotherapy, Vol. 32, No. 7, pp. 997-1001 (1998)

Martin et al. (Martin), "High Dose 5-Fluorouracil with Delayed Uridine "Rescue" in Mice," Cancer Research, Vol. 42, pp. 3964-3970 (1982)

Bhalla et al. (Bhalla), "Deoxycytidine Preferentially Protects Normal Versus Leukemic Myeloid Progenitor Cells from Cytosine Arabinoside Mediated Cytotoxicity," Blood, Vol. 70, No. 2, pp. 568-571 (1987)

Falcone et al. (Falcone), "Differential Effect of Benzylacylouridine on the Toxic and Therapeutic Effects of Azidothymidine in Mice," Blood, Vol. 76, No. 11, pp. 2216-2221 (1990)

Grounds of Rejection

Claims 1-15, 18, 19, and 22-25 stand rejected under 35 U.S.C. § 103 as obvious over Martin or Sommadosi in view of von Borstel and Falcone.

Claims 16-17 and 20-21 stand rejected under 35 U.S.C. § 103 as obvious over Bhalla in view of von Borstel and Hanze.

We remand the application to the examiner.

DISCUSSION

Rejections under 35 U.S.C. § 103

Claims 1-15, 18, 19, and 22-25 stand rejected under 35 U.S.C. § 103 as obvious over Martin or Sommadosi in view of von Borstel and Falcone. Claims 16-17 and 20-21 stand rejected under 35 U.S.C. § 103 as obvious over Bhalla in view of von Borstel and

Hanze.

The statements of rejection which appear in the Final Office Action are not susceptible to meaningful review. The rejections encompass a plurality of claims but do not state with any specificity why any individual claim is unpatentable. If the examiner maintains a rejection under 35 U.S.C. § 103, we suggest the examiner review Manual of Patent Examining Procedure (MPEP) § 706.02(j) for a model of how to explain a rejection under this section of the statute. Adherence to this model will of necessity require that the examiner consider the patentability of the claims in an individual manner and set forth the facts and reasons in support of why individual claims are unpatentable.

The statement of rejection should include a clear statement of the specific understanding or principle within the knowledge of a skilled artisan, explicit or implicit, that would have motivated one with no knowledge of appellants' invention to make the combination in the manner claimed. In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457 (Fed. Cir. 1998). More specifically, the examiner should clearly provide an indication of the motivation to combine the teachings of Martin or Sommadosi in view of von Borstel and Falcone to arrive at a method of preventing or treating toxicity due to a pyrimidine nucleoside analog. The examiner should clearly address appellants' arguments regarding lack of motivation to combine the cited references as presented in the Brief, pages 7-10. The examiner should similarly address appellants' comments regarding the combination of Bhalla in view of von Borstel and Hanze, stating with

specificity why each separately argued claim is unpatentable. The examiner should also take into account the allowed patents set forth in the obviousness-type double patenting section below.

Unexpected Results

The appellants argue that Example 6 of the specification pages 42-44 evidences unexpected results obtained with the method of the present invention. Brief, page 7. The examiner has not considered these results, alleging the information was not in the specification or affidavit form. Answer, page 12. The examiner's statement is not understood as Example 6 does appear in the specification. Examiners must consider comparative data in the specification which is intended to illustrate the claimed invention in reaching a conclusion with regard to obviousness of the claims. See, In re Margolis, 785 F.2d 1029, 228 USPQ 940 (Fed. Cir. 1986); MPEP 716.01(a). In addition, the examiner has not responded to appellants' arguments concerning two publications, Kralovansky and Kellen. Brief, page 8. If the appellants have not provided these publications for the examiner's review, this should be noted on the record. If the publications have been provided for the examiner's review, their consideration should be noted by the examiner. Upon return of the application to the examiner, the examiner should properly consider evidence of unexpected results provided in the specification and any appropriate publication evidence provided to the examiner.

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Obviousness-type Double Patenting

Upon return of the application to the examiner, the examiner should revisit the obviousness-type double patenting rejection over five co-pending applications¹, which was held in abeyance in final rejection. Paper Nos. 5 and 15. The examiner should determine whether any of the other patent applications have issued, and make an appropriate rejection for each, as necessary. The examiner should specifically indicate which claims of the present application are rejected for obviousness-type double patenting in view of specifically indicated claims of U.S. Patent No. 5,968,914 issuing from Application No. 08/464,944. The examiner should also review U.S. Patent Nos. 5,770,582 and 5,736,531 and determine any relevance of these patents to the patentability of the pending claims.

Other Issue

In the Supplemental Reply Brief, pages 1-2, the appellants indicate they have become aware of a relevant publication, Calabresi. Upon return of the application to the examiner, the examiner should consider the relevance of Calabresi to the pending claims.

We state that we are not authorizing a Supplemental Examiner's Answer under the provisions of 37 CFR § 1.193(b)(1). Any further communication from the examiner

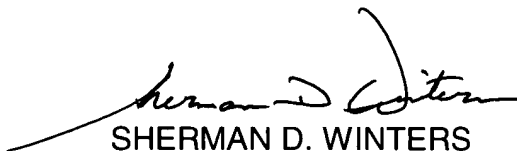
¹ Note only four provisional double patenting rejections are repeated in Paper No. 8. Clarification by the examiner is recommended.

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which contains a rejection of the claims should provide appellants with a full and fair opportunity to respond.

This application, by virtue of its "special" status, requires an immediate action. MPEP § 708.01 (7th ed., rev. 1, February 2000). It is important that the Board be informed promptly of any action affecting the appeal in this case.

REMANDED


SHERMAN D. WINTERS
Administrative Patent Judge


WILLIAM F. SMITH
Administrative Patent Judge


DEMETRA J. MILLS
Administrative Patent Judge

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